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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
08-950,963	10/15/1997	JOEL A. DREWES	074022-3302	9997

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EXAMINER

MARSCHEL, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 12/27/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/950,963

Applicant(s)

Drewes et al.

Examiner

Ardin Marschel

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Aug 28, 2002

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-50 is/are pending in the application.

4a) Of the above, claim(s) 13-17 and 35 is/are withdrawn from consideration

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-12, 18-34, and 36-50 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-50 are subject to restriction and/or election requirement

Application Papers

9) ☒ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) : Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s).

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s).

6) ☐ Other:

The art unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence should be directed to Art Unit 1631.

Applicants' arguments, filed 8/28/02, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. It is noted that this appears as the second sentence of the specification following the title, as a separate paragraph. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. _____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. No status for application serial number 08/742,255 is shown in said second sentence of the instant specification.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The present title includes broad, generic, methods and devices but such generic methods are not presently under examination. In contrast only laminar flow providing, or diamond-like carbon attachment layered, devices are claimed as well as only methods for the construction of such devices.

Claims 1-12, 18-34, 36-40, and 42-50 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been amended to require that a device of the above listed claims provides "laminar flow" of sample. This newly added set of claim limitations causes the claims to be vague and indefinite. One possible interpretation of the above listed claims is that a device is being claimed wherein channels and layers are configured so that, when a sample is present, laminar flow therethrough is possible, but that a sample is not necessarily present in the claimed device. A second interpretation is that a sample must be present in the claimed devices wherein laminar flow is occurring as a required condition for the claimed subject matter. It is noted that laminar flow

pre se requires actual flow of sample in order for this characteristic to be present. It is noted that devices of the instant claims seemingly worded so as to provide laminar flow and are not worded so as to be configured and arranged to merely permit laminar flow. The above two interpretations conflict regarding what the metes and bounds of the claims are.

Claim 36 is vague and indefinite regarding the listing of analytes therein in that the phrase "inorganic or organic compounds" in the last line seems to encompass all compounds types which is redundant compared to the other listed selections, such as antigens, antibodies, etc. Are the "inorganic or organic compounds of some differing type from those listed previously in the claim? Clarification via clearer claims wording is requested.

Claims 42 and 43 are vague and indefinite regarding the limitations therein given by the phrase "analogs or derivatives thereof". As worded in the claims an analog or derivative could be anything due to a lack of limitation as to what alterations define the metes and bounds of such entities. It is noted that unlimited deletion, substitution, and addition may result in the change of any item into any other item. What defines an analog or derivative as present in claims 42 and 43? Clarification via clearer claim wording is requested.

Claim 39 is vague and indefinite in that the preamble of

claim 39 indicates that an assay device is being claimed but confusingly there are no device limitation(s) in claim 39 which mediates assay usage. Are the metes and bounds of claim 39 limited via the preamble or are the metes and bounds limited only via lines 3-5 of claim 39 which cites nothing for analyte interaction for assay purpose(s). It is noted that an attachment layer may result in the attachment of a variety of materials including non-assay mediating materials. An assay device is expected to require some type of analyte binding ligand thereon or interactive material. None of lines 3-5 of claim 39 contains such a ligand or material. Clarification of the claim metes and bounds is requested via clearer claim wording. Claims which are directly or indirectly dependent from claim 39, which also lack analyte binding or interacting limitations in the claimed device are thus also vague and indefinite for the same reasons as discussed above. It is also noted that this unclear conflict of metes and bounds also is present in instant claims 2, 4, 6-12, 19-22, 36-38, 40, and 44-50.

Claim 18 is vague and indefinite in that line 5 cites an attachment layer which is "on said optically functional layer". As depicted in instant Figure 1, the receptive layer/material of the instantly disclosed devices, which is apparently for utilization for analyte interaction, is positioned on the attachment layer and not directly positioned on the optically

functional layer. Claim 18, lines 5-6, cite an attachment layer as in said Figure 1, but, in contrast, indicates that the analyte specific receptive layer per se is provided "on said optically functional layer". This positioning of the analyte specific receptive layer directly on the optically functional layer is a limitation which is not commensurate with the description of the devices of the instant invention as in Figure 1, or, as further discussed in corresponding specification descriptions.

Clarification of the metes and bounds of the instant invention is requested via clearer claim wording. Claims which are dependent directly or indirectly from claim 18 are also included in this rejection as vague and indefinite for the reasons discussed above.

Claim 1 cites the laminar flow of sample through each layer of the claimed device "via said channels". Two possible interpretations of these limitations are possible. Firstly, the flow through the layers may occur "via said channels" because of channels which are within the layers themselves such as cutouts within otherwise flat or planar layers. Secondly, the channels may provide flow through said layers by being outside of the layers and delivering sample to each layer for flow through. These two interpretations are different regarding what type of device is being claimed. Thirdly, are the channels which provide laminar flow actually pores within each layer which is thus a

porous layer? Clarification via clearer claim wording is requested. All of instant claims 1-12, 18-34, and 36-38 either directly or indirectly via depending from independent claims contain this unclarity.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5, 6, 9, 18-20, 22-24, 26, and 36 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Brecht et al. [Anal. Chim. Acta. 311:289(1995)].

This rejection is reiterated and maintained from the previous office action, mailed 5/6/02. Applicants argue that the Brecht et al. reference was previously acknowledged in Paper No. 11, part 2, as not providing true laminar flow. Both said section of Paper No. 11 as well as Brecht et al. have been reconsidered as to disclosures in the reference as well as the evaluation of such disclosures in Paper No. 11. No support in Brecht et al. has been found which states, recognizes, or even suggests that the laminar flow cell description therein is anything other than a laminar flow cell disclosure. Thus, the

Office action, mailed 7/20/00, is confusing on this point and apparently inconsistent with the laminar flow cell disclosures in Brecht et al. It is hereby set forth that the teachings of the reference, Brecht et al., clearly disclose a laminar flow cell, its preparation and use and thus properly supports this rejection. Said evaluation regarding none true laminar flow as set forth previously in said Paper No. 11 is hereby withdrawn.

Applicants then argue that the laminar flow of Brecht et al. is not "through" the layers of the device via channels, but rather, across the device surface lacking channels with exiting at an opening in a surface of the device lacking any of the layers of the instant claims. Applicants also argue that no channels are present on the chip in Brecht et al. In response, the depiction of Fig. 2 on page 292 of Brecht et al. clearly shows channels for inlet, outlet, and, as well, delivering sample flow to the analyte/optical layers of the device. Also, given the unclear wording of the instant claims as discussed in the above 112, second paragraph, rejections, the providing of flow through the layers is provided by channels which provide said flow to the layers as in Brecht et al. as depicted, for example, in Fig. 2 on page 292. Applicants then argue that the previous office action in Paper No. 23 indicated that laminar flow is inherent in linker/analyte type attachment layers. In response the word "inherent" has not been found in the entirety of said

Paper No. 23 office action. Further in response the linker/analyte type attachment layers as being similar to blades of grass waving in a current in a lake of river was previously set forth in order to effect a better explanation of the laminar flow practice of the reference and not that the mere disclosure of an attachment/analyte layering is "inherently" laminar flow providing. In summary this rejection is still deemed proper and additionally applied to other instant claims which are directed to a claimed device which has the layers for optical function, attachment, and optionally include analyte specific receptive layering. It is noted that the device depicted in the reference on page 292, Fig. 2, contains inlet and outlet which are reasonably also viewed as pores in the support of the device, thus disclosing a "porous support, as required in instant claims 3-6. Instant claim 9 is included as rejected because page 292, bridging paragraph between the left- and right-hand columns, disclosed glycerol as layered at the underside of the device, deemed to be beneath the support which is a liquid and is at least somewhat light absorbent as all such liquids are. It is noted that instant claim 9 is not clearly worded as to what absorbency is meant in line 2 therein. Claim 22 is included as rejected here also because the porous support limitation is anticipated as noted above and the glycerol layering is reasonably in a channel which is also reasonably associated or

contained in the optically functional layer for index matching as noted in the reference on page 292, second column, lines 1-3.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1, 2, 5, 6, 9, 18-20, 22-24, 26, and 36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Oberhardt (P/N 4,849,340).

This rejection is reiterated and maintained from the previous office action, mailed 5/6/02. Applicants firstly argue that the optically functional layers of the instant invention, as defined in the specification on page 10, lines 4-23, are not inclusive of the practice of using labeled species but rather

"solely" from binding of material to the surface in contrast to the Oberhardt described practice. Firstly, in response consideration of said page 10 description has failed to reveal any limitation to support this above noted "solely" practice. Thus, applicants' argument is contrary to the factual evidence in the instant specification and thus non-persuasive. Secondly, said page 10 discussion does, in fact, include generically optical signaling upon analyte binding without limitation. Thus, a labeled entity either attached to analyte or a competitive labeled reagent usage is included as part of optical functioning of the optically functional layer of the instant invention. Applicants then argue that statement made in the file history must be considered in interpreting claim limitations. In response, it is acknowledged that file history arguments must be considered, but that the basis of the invention with any lexicography set forth, as filed, is the determinative guide for claim limitations and not "added" lexicographic definitions submitted later in the file history. The invention as filed must be the guide because, if new lexicography is determinative of claim interpretation as added during the file history after filing, then any applicant would be able to alter an invention disclosure arbitrarily via new lexicography. This would contribute to serious and counter-productive confusion as to what an invention disclosure is meant to convey. In summary, new

lexicography after filing is non-persuasive to add new claim interpretations. Thus, the invention disclosure as filed as it supports the instant claim limitations is not distinguished over Oberhardt as previously set forth and reiterated here with further explanation.

Applicants further argue that the selection of components from the reference is not obvious due to there being therein no knowledge as to why the skilled artisan would have selected "these components" in the manner claimed. In response, a generic disclosure of clearly set forth options is deemed for obviousness purposes to motivate and suggest the selection of any of the options therein.

Claims 1-7, 18, 19, 21, 23, 25, 36, and 38-43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Walt et al. (P/N 6,023,540).

This rejection is reiterated and maintained from the previous office action, mailed 5/6/02. Applicants argue that priority to the parent application; serial number 08/742,255; predates the Walt et al. reference. In response, the instant application is a continuation-in-part from said parent 08/742,255. Thus, applicants' allegation of priority to said parent has been set forth without factual support such as pointing to support for the instant claims in said parent. Such an allegation without factual support is non-persuasive. Written

support also has not been found by the Examiner for priority to said parent application.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5-12, 23, 24, 26-34, and 36-50 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51, 52, 54, 55, 57-63, 66-68, 70, 71, 73-79, and 82 of copending application Serial No. 09/675,518. Although the conflicting claims are not identical, they are not patentably distinct from each other because the supports claimed in said copending application are not merely supports but also contain layers as instantly claimed. For example, claim 54 of 09/675,518 requires an antireflective layer of diamond-like carbon as well as the support and attachment layer of claim 51 due to its

dependence from claim 51. These are embodiments within instant claim 39. Such combinations of limitations are therefore also present in independent claims due to dependent claims therefrom. It is noted that the particle limitations of certain instant claims, however, are not present in the claims as listed above from the copending application. No argument has been directed specifically to this rejection which is therefore maintained from the previous office action due to the non-allowability of the instant claims.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

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Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 26, 2002

Ardin H. Marschel
ARDIN H. MARSCHEL
REGISTERED PATENT EXAMINER